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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,687

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Elka Touitou

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EXAMINER

YU, HONG

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

01/25/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/591,687	Applicant(s) TOUITOU, ELKA	
	Examiner HONG YU	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/15/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

The amendment filed on 10/25/2009 is acknowledged. Claims 1-18 have previously been canceled and new claims 36-46 are added. Claims 19-46 are under examination in the instant office action.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to applicants' arguments relevant to either reiterated or newly applied rejections.

New ground of rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 19 uses an open-ended word “comprising” which opens for inclusion of unspecified ingredients even in major amount. Therefore, claim 19 is interpreted as “a method for treating a burn comprising applying to the burned area a composition comprising ethanol, polymeric carrier, and other components”.

Claims 19-24, 30, and 34-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. (US 2003/0027833 A1).

Applicant's claims

Applicants claim a method for treating a burn comprising applying to the burned area a gel composition comprising 15-50%, 20-50%, 20-40%, about 20%, about 30%, about 35%, about 40%, about 45%, and about 50% by total weight of ethanol, a topically acceptable acrylic polymeric carrier, and urea (see claims 19-21, 30, 34, and 39-45), wherein the treatment impedes micro-vascular destruction and progression associated with the burn.

Claims 22-24 recite the said polymeric carrier is carbomer as a polyacrylate.

Claim 35 recites the composition further comprising one or more ingredients selected from a local anesthetic, antibiotic, etc.

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Claim 36 recites the said polymeric carrier comprises one or more of the following polymer: polyvinyl alcohol, gum, gelatin, pectins, etc.

Claims 37 and 38 recite the burn is caused by a scald and the burn is a second degree burn.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

Cleary et al. teach a method of treating burn (paragraph 101) comprising topically applying a composition comprising from about 1 to about 40% by weight of ethanol (paragraph 63), polymer or mixture of polymers (claim 16), and anesthetic (paragraph 47).

Cleary et al. teach the said polymer being carbomer (a polyacrylate) and polyvinyl alcohol (claim 16).

Cleary et al. teach that the composition further comprises urea (paragraph 65).

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

Cleary et al. do not specify the burn to be treated is caused by a scald and is a second degree burn.

Cleary et al. do not specify the treatment impedes micro-vascular destruction and progression associated with the burn.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

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A burn is a type of injury caused by heat. Scald is a type of burn caused by hot liquids or gases, and a second degree burn is used to describe the severity of burn. It would be reasonable to assume that the burn to be treated that is disclosed by Cleary et al. should include a burn caused by scald and a second degree burn.

With regard to the treatment impeding micro-vascular destruction and progression associated with the burn, Cleary et al. teach a method of treating burn with the same topical composition recited in the instant claims. It would have been prima facie obvious that impeding micro-vascular destruction and progression associated with the burn takes place under the treatment taught by Cleary et al..

Claim 25-29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. (US 2003/0027833 A1), and further in view of Rhodes et al. (US 6,071,959).

Applicant's claims

Claims 25-29 recite a polyacrylate with concentration of 0.05-5% being neutralized by ammonium hydroxide with concentration 0.1-10% and triethanolamine with concentration of 0.1-6%, respectively.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

The teachings of Cleary et al. are discussed above and applied in the same manner.

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

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Cleary et al. do not specify the neutralizing agent used to neutralize polyacrylate being **ammonium hydroxide or triethanolamine**, respectively; and the amount of polyacrylate and the amounts of ammonium hydroxide and triethanolamine; [REDACTED]

[REDACTED]

This deficiency is cured by Rhodes et al. who teach 0.1 to 2% of carbomer (column 5, line 44) being neutralized by **sodium hydroxide, ammonium hydroxide, or alkanoamine** (column 8, line 13-19).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Cleary et al. and Rhodes et al. to substitute sodium hydroxide with ammonium hydroxide or triethanolamine as a pH regulator in the composition disclosed by Cleary et al.. Sodium hydroxide, ammonium hydroxide, and alkanoamine were well known as equivalent pH regulators (neutralizers) as taught by Rhodes et al.. It is generally considered to be prima facie obvious to substitute a component with another which are both taught by the prior art to be well known and useful for the same purpose in order to form a composition that is to be used for an identical purpose. (As shown by the recited teachings, the instant claims are no more than substituting a conventional pH regulator (sodium hydroxide) with other pH regulators, such as ammonium hydroxide or triethanolamine. It therefore follows that the instant claims define prima facie obvious subject matter.

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The amount of a pH regulator in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of a pH regulator to be used in order to reach a pH of 9.0 or higher. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of the amount of pH regulator would have been obvious at the time of Applicants' invention.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Cleary et al. and Rhodes et al. to choose the amount of polyacrylate as 0.1 to 2% by weight in the composition disclosed by Cleary et al.. Choosing 0.1- to 2% by weight of polyacrylate in a gel formulation would have been suggested to a person of ordinary skill in the art at the time of the invention.

Claims 31-33 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. (US 2003/0027833 A1), and further in view of Jensen (US 5,958,420).

Applicant's claims

Applicants claim the formulation further comprising plant derived materials such as derived material from a tea tree (see claims 31-33).

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Claim 46 recites the said composition is used within about one hour of burn onset.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

The teachings of Cleary et al. are discussed above and applied in the same manner.

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

Cleary et al. do not specify addition of derivative materials from plants such as tea tree, but specify one or more additional active agents such as essential oils can be included (paragraph 50 and 53).

This deficiency is cured by Jenson who teaches a method of treating burn (column 4, line 15-18) with a composition comprising tea tree oil and carbomer (column 6, line 29 and 58).

Cleary et al. do not specify application of the burn-treating formulation within one hour of burn onset.

This deficiency is cured by Jenson who teaches applying a burn-treating formulation immediately (column 13, line 23-25).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Cleary et al. and Jenson to choose

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tea tree oil as a component in the composition disclosed by Cleary et al.. Tea tree oil is well known as an essential oil to a person of ordinary skill in the art at the time of the invention. It is generally considered to be prima facie obvious to choose a component which is taught by the prior art to be well known and useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for choosing it flows from its having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, the instant claims are no more than specifying a conventional essential oil. It therefore follows that the instant claims define prima facie obvious subject matter.

With regards to " application of the burn-treating formulation within one hour of burn onset; it is intuitive and a common practice to treat a burn condition as soon as possible. Jenson also specifies applying a burn-treating formulation immediately.

Therefore, it would be prima facie obvious for a burn to be treated as soon as possible which includes within one hour of burn onset.

Response to Arguments

Applicant's arguments, filed on 10/15/2009, have been fully considered but they are moot in view of new ground of rejections.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Yu whose telephone number is 571-270-1328.

The examiner can normally be reached 8:50-6:50 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./
Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616